



#04-7984

P.C. 840016

**LifePoint, Inc. Written Response to
Mandatory Guidelines for Federal Workplace
Drug Testing Programs
FR Doc 04-7984**

July 12, 2004

**LifePoint, Inc.
1205 South Dupont Street, Ontario, California, 91761
Telephone: 909.418.3000 Facsimile: 909.418.3003**

LifePoint, Inc. (Ontario, Calif.) has developed and is now marketing a unique on-site product that tests for both alcohol *and* drugs without the use of breath, blood or urine (see Exhibit A). The LifePoint® IMPACT® Test System uses flow immunosensor technology, for which the company holds an exclusive worldwide license from the United States Navy Research Laboratories. When used in conjunction with saliva as the test specimen, this unique technology has made it possible for LifePoint to develop a broadly applicable, non-invasive, on-site diagnostic test system that is capable of collecting a saliva sample and providing completely automated results for up to 10 analytes in minutes.

As this new technology and others apply to testing for substances of abuse in the workplace, the LifePoint IMPACT Test System brings the advantages of observable, non-invasive sample collection, that should prove to be evidential for alcohol with significantly more sensitive and specific drug test results than that provided by current urine based drug tests (either on-site or lab based). The system is completely automated to provide legally defensible, operator-independent results. All of these benefits have been proven in a variety of testing environments to provide significant cost savings and operational improvements for testing substance abuse in the workplace.

During the past several years, LifePoint has presented its technical findings at numerous conferences and seminars. LifePoint has presented at the Drug and Alcohol Testing Industry Association, the International Chiefs of Police Drug Recognition Expert Conference, the Mid-Atlantic Association of Forensic Toxicologists, the Northwest Association of Forensic Toxicologists, the International Association of Forensic Toxicologists, the International Congress of Alcohol, Drugs and Traffic Safety, the European Union project on roadside drug testing (the ROSITA project), the Society of Forensic Toxicologists, the American College of Emergency Physicians, and the Office of National Drug Control Policy. In all instances, LifePoint's presentations have been well received. Audiences of employers, law enforcement officials, government representatives, medical professionals, scientists and researchers had consistently shown a great deal of interest in the flow immunosensor technology and the first product now being marketed by LifePoint.

More importantly, customers are enthusiastic about using the product. LifePoint has customers in various market segments already using the product with excellent results, including driving under the influence of drugs or alcohol testing in the United States and in Europe, drug courts, probation and parole, and for employee testing.

With such a tremendously positive response to the LifePoint's saliva-based, on-site simultaneous test for drugs of abuse and alcohol, we feel it necessary to comment on the recently published "Mandatory Guidelines for Federal Workplace Drug Testing Programs." While we acknowledge that the Guidelines' initial purpose is to establish standards applicable to the testing of certain federal employees, it is important to note the impact that such guidelines may have on

non-mandated, private sector drug testing practices. Numerous state drug-testing laws have adopted the Guidelines, with modifications, for mandatory use by employers operating in those states. Countless private sector employers have structured and will continue to structure their own corporate drug testing policies around the provisions contained in the Federal Government's Guidelines. It is critical therefore, for SAMHSA to take into consideration the availability of these newer technologies and products that are revolutionizing workplace testing practices, and finally provide the ability to easily obtain on-site lab-quality results quickly and cost-effectively.

We recognize the continued effort that this draft represents on the part of the SAMHSA/CSAP Division of Workplace Programs and the members of the SAMHSA Drug Testing Advisory Board (DTAB). While we recognize that this draft may be final, there remain some significant issues that still need to be addressed. We appreciate the opportunity to submit these additional comments and respectfully petition your full consideration of the following.

On-site Testing (POCT)

The use of simple, easy-to-use on-site drug testing products have been proven to enhance current workplace substance abuse prevention programs and allow for more cost-effective and faster testing methods while not jeopardizing the integrity of such programs. Although these draft guidelines include these new and improved technologies, the guidelines themselves continue to be biased very heavily in the direction of labs and MROs. In fact, many of the draft guidelines require much greater quality control, validation, inspection and certification for on-site products than what are currently required of laboratories and the MRO review process. This is unduly onerous and unfair, especially in light of the fact that numerous studies have shown that these new products and technologies provide the same level of accuracy as laboratory based testing. In fact, the draft guidelines themselves, in the introductory section state that "Non-instrument POCT for urine testing have been subjected to evaluations by investigators independent of the manufacturers and found to perform similar to that of the instrumented immunoassay tests in certified laboratories.Little difference in the performance of these (Non-instrumented POCT) devices was observed between tests conducted by laboratory technicians and laymen who had been trained in the proper procedure for conducting and reading the tests."

Currently DTAB consists of service providers, employers, laboratorians, and MROs. Conspicuously absent are any representatives from the manufacturers of the products, which, based on these proposed guidelines, will now be unduly regulated. We strongly recommend that at least one, and perhaps two representatives from the manufacturers of the POCT devices be added to DTAB. Often the proposed guidelines indicated unfamiliarity with requirements manufacturers already meet for FDA and other regulatory agencies, and even unfamiliarity with the products themselves – especially as it relates to the accuracy and precision of the product based on detailed third-party data.

The current mandate for the federal government is to use the “least burdensome approach”. Many of the proposed guidelines for POCT are overly onerous and burdensome. We continue to strongly recommend the use of a regulatory approach that is modeled on the utilization of on-site breath alcohol tests, which have been used effectively and efficiently for over 40 years.

These guidelines continue to use a general approach that significantly increases the cost of the drug testing process without increasing the overall accuracy and effectiveness of the program. If the goal of these guidelines is to improve the overall accuracy, effectiveness, efficiency and speed of the testing process, then the use of lab-oriented regulations, oversight and inspection requirements for such simple on-site testing products is overkill. We need only look back to the late 1980s to see how such over-regulation can actually harm the public good rather than help it. Prior to the implementation of the Clinical Lab Improvement Act of 1988 (CLIA-88), most physician offices performed a wide variety of tests that enhanced the physician’s ability to provide immediate diagnosis to their patients. The patients and physicians both enjoyed the benefits of this process. With the passage of CLIA-88 and the requirement for physician office labs to meet the same standards as commercial labs, 85% of physician offices doing on-site testing stopped (CDC data).

We strongly object to the SAMHSA proposed requirement that the donor NOT observe the test being conducted. The US Postal Service provided testimony at a previous DTAB meeting indicating that they have done over 50,000 on-site tests and have had NO complaints or problems with the testing being done with the donor present. Nearly 6 years later there is no evidence of confrontations. In fact, the US Postal Service and the United Transportation Union testified that they prefer the testing be done with the donor present since they can then be certain that the sample tested is theirs and that a mix-up of specimens has not occurred.

Additionally, the alcohol testing programs being used by the same service providers for industrial testing have been performing tests with the donor present for years, and have not reported a problem.

That the donor is present or not during testing should be an option selected by the employer or service provider. The suggestion that the donor be absent during testing may, in fact, be in direct conflict with many employee union requirements and even the DOT. This requirement will also cause a problem with integrated devices—which has been one of the “want to have” features of products, since it eliminates the possibility of misidentification and the need for COC. Many studies have shown that one of the biggest sources of error in laboratory testing is sample mis-identification or results mix-up. Studies have shown this error rate to be an average of 5% in laboratory testing. Using an integrated system that collects, tests, and provides instrumented results with little possibility of either a mix-up in specimens or test results will have a significant positive impact on

improved accuracy for the total testing system. The incorporation of a fully integrated collection, testing, reporting system can actually do more to improve accuracy than a better test method might.

Additionally, the proposed guidelines fail to take into consideration newer technologies and products that provide lab-quality results with the added benefits of speed and simplicity. Such products, with FDA clearance, would qualify for CLIA waived status and allow for lab-quality results that can be generated by non-laboratory personnel. We recommend that the guidelines take such products into consideration - they improve the cost-effectiveness and efficiency of the drug testing process.

Lastly, the proposed guidelines show continued failure to recognize the technical fact that there are compositional differences between different specimen types, including alternative specimens, and the metabolic distribution of drug metabolites over time. We hope the final proposed rule corrects these failings.

We respectively provide the comments below in order to *improve* the efficiency and effectiveness of the current processes, not cement the current process to unnecessarily protect or increase the market position of laboratories and MROs.

Saliva Testing

Numerous studies have shown that saliva as a drug test specimen represents a viable alternative for drug testing programs. Additionally, the use of saliva rather than urine makes it possible to address a number of burdensome issues that have plagued drug testing for many years. For example, saliva is, by far, a much less invasive specimen for collection purposes. Few people find it offensive to provide a saliva sample versus urine. Saliva also makes it possible to conduct an observed collection *every time* while urine would requires an observed donation to obtain the same assurance of sample integrity.

Interest in the use of saliva for drug testing purposes is growing rapidly and the guideline should not only reflect this, but also be careful not to inadvertently restrict or discourage its use. This is especially true at a time when adulteration and substitution problems associated with urine testing are beginning to impact the integrity of the drug testing process overall, and the provision of a specimen that can be observed every time significantly reduces the opportunity for substitution and adulteration.

Because saliva has a narrow window of detection time, depending on the drug, dosage level, sensitivity of the detection method, and the donor's metabolic rate, saliva makes an excellent indicator of "under the influence" status, particularly effective as an accurate post-accident, reasonable suspicion test, or a fit-for-duty test. Additionally, all urine and saliva-based drug tests are "recent use" tests and as such have the capability to be used for pre-employment, random, and return-to-duty testing; in fact, with some drugs (e.g., cocaine, amphetamines and THC),

depending on dose level and assay sensitivity, the window of detection for saliva will overlap that of urine (Cone, Edward J. in Malamud, D. and Tabak, L. (eds) Saliva as a Diagnostic Fluid. "Saliva Testing for Drugs of Abuse", Annals N.Y. Academy, Sci., vol. 694 (1993), pp. 91-127).

Saliva has already been validated and approved in many states as a viable specimen for use in the criminal justice system, for all drugs, including THC (without any passive inhalation issues). Additionally, several participants in the European Union-funded ROSITA project have published the results of their studies and have defined the "perfect on-site drug test" as a saliva-based, instrumented (for objectivity and elimination of user interpretation), panel test, with results in 5 minutes.

The Guidelines Point-by-Point

The following are recommendations that LifePoint believes should be considered as SAMHSA finalizes the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

§1.5 What do the terms used in these Guidelines mean?

The definition of a "**Negative Result**" should be changed to: "The result reported by an HHS-certified laboratory, IITF, or POCT tester to the employer when a specimen contains no drug or the concentration of the drug is less than the cutoff concentration for that drug or drug class." The requirement found in Section 12.22, "How is a POCT negative result reported?", is one of the most burdensome and unnecessary requirements relative to the entire drug testing process found in these guidelines. **There is no legitimate, functional reason to have MROs review negative results.** The fact that this section allows for up to 3 working days to transmit such results to MROs is evidence of the requirement's utter wastefulness. For what possible purpose would an employer need to have an MRO review a 3-day old negative test result? There is none and yet **this would add significant cost burden to the employer** – especially in light of the fact that 96% of the tests completed are negative (Quest Diagnostics published data, 2000). The choice of using an MRO in this role should not be dictated by SAMHSA but should be left to the discretion of the employer.

The definition of "**Non-Negative Result**" should be changed to: "The result reported by an HHS-certified laboratory when a specimen is either adulterated, substituted, or contains a drug or drug metabolite." **We strongly recommend the use of the term "Presumptive Positive."** The accepted term for FDA Drugs of Abuse Prescription Use Testing is "presumptive positive" and all products that already have FDA clearance use this term. More problematic is that fact that the term used in the FDA proposed guidelines for the Workplace testing is also "Presumptive Positive" **It is impossible to use two different terms simultaneously for the same test result, particularly since the newly**

proposed term is self contradictory! The requirement to use two different terms to report the same test result to employers and laboratories will be confusing and onerous to the end users, manufacturers and distributors of the products, both on-site and in the laboratory. As a note, in section § 12.18 (e) presumptive positive, not non-negative is used.

§ 2.3 Can more than one type of specimen be collected at the same time from the same donor?

It is blatantly onerous and unfair to require the collection of a urine specimen anytime an oral fluid sample is collected. No other specimen type has this requirement, even though each other type of specimen has its own advantages and disadvantages for collecting and testing samples. The major advantage of oral fluid samples are that they do NOT require special facilities for a collection, such as is required for urine, and that the sample collection is always observed so that the ability to adulterate or substitute a specimen (as commonly occurs with urine specimens) is virtually eliminated.

The purported reason for requiring a urine sample is a concern that THC positive oral fluid samples may produce false-positives results due to passive inhalation. This assessment is NOT technically correct and not validated by studies completed to date. Previous studies have shown that even in the presence of highly concentrated amounts of THC smoke, a person's urine does NOT become contaminated (E. J. Cone et al. J. Anal. Toxicol. 11: 98-96, 1987). More recent data, generated by OraSure, shows that even when a person breathes air heavily laden with THC smoke, the oral fluid does not test positive within minutes (R.S.Niedbala et al. Journal of Analytical Toxicology vol. 25, pp 289-303, 2001). If a person tests positive for THC and claims that they were subjected to second hand smoke within the last 20-30 minutes, a second test can be performed in 30 minutes. Keep in mind that in the industrial workplace, less than 4% of the specimens are positive. Therefore, the requirement to collect a urine sample with every oral fluid is overly burdensome and unfair. Also unnecessary is the requirement to perform a urine THC test on all oral fluids that test presumptive positive for THC. It is very possible, that due to window of detection differences for THC in urine versus oral fluid, the same person can legitimately test positive for THC in oral fluid and have a negative urine. Therefore, any use of urine to validate an oral fluid sample for THC is burdensome, onerous and unfair

If SAMHSA does not believe the results of these studies, and requires testing on an alternative specimen type, then the guidelines should be changed to collecting a urine specimen ONLY when an oral fluid specimen initially tests positive for marijuana; and NOT collected with every oral fluid sample. The burden of proof is to verify that an initial positive result is positive, and not to search for positive test results.

§ 2.4 How is each type of specimen to be collected?

It is unnecessary and overly burdensome to the donor to collect a split sample for every specimen collected when a POCT test is done. The significant benefit and cost effectiveness of on-site testing with a POCT device is the ability to eliminate the need to send sample with an initial negative result to the laboratory. It should be sufficient to collect a split sample **only** when a non-negative (or presumptive positive) result is obtained on a sample.

Although we can understand why it may be desirable to prevent the donor to have un-controlled access to a test device, there are many reasons why an integrated collection and test unit is highly desirable, and will improve the overall accuracy and efficiency of the testing process.

One of the biggest sources of error in laboratory testing is the sample mis-identification or results mix-up. The use of an integrated system that collects, tests, and provides an instrumented results with no possibility of either a mix-up in specimens or test results will have a significant positive impact on improved accuracy for the total testing system. In most cases, the test device itself is a closed unit, and even if the person had access to it, it cannot be tampered with without evidence of tampering. Additionally, integrated collection, processing, and results have been used for years very positively in the breath alcohol-testing mode.

Lastly, no sample handling is one of the requirements for a product to be CLIA waived, which means that it improves the level of accuracy and eliminates one of the major sources of errors in testing by non-laboratory personnel.

In addition, in the case of the integrated test cups, such as those offered by Roche or Dade Behring, the test strips are isolated and sealed in a part of the cup where the donor cannot touch or interfere with the test strips. Our concern is that by requiring the collector to use a separate collection cup, an unnecessary step is being required. The donor should be able to void right into the test cup.

With an oral fluid integration collection and test device for POCT, it is impractical to not have the donor be present and hold the device. Why not require observed collection instead for oral fluid products. This is the best scenario for oral fluid.

We recommend that the requirement that the donor must not have access to the test device or not be present when the testing be performed be eliminated when the device has a tamper-proof design and/or the donor does not have un-controlled access to the test device (the tester is present when the collector/test device is being used and/or the donor does not touch the test device as would occur in saliva testing).

§ 2.5 What is the minimum quantity of specimen to be collected for each type of specimen?

For urine testing, obtaining more sample than is needed for any testing technology alternative is usually not a problem, but for other samples such as

saliva/oral fluids, sweat, and hair, the required amounts can vary significantly for each type of initial test technology and even for the confirmation. For example, the sample volume requirements for GS/MS and GS/MS/MS and LC/MS vary significantly from each other and can also vary by laboratory, and may often influence the sensitivity and specificity of a test result. This requirement needs to be technology driven to meet the cutoff requirements of the Guidelines, and should not be defined by SAMHSA but rather by the practices of the laboratory that provides the testing service.

With the exception of urine testing, where sample volume is not an issue, the on-site test sample requirements, both volume and type of sample (processed or preserved in some way) should be left to the manufacturer of the initial test and laboratory requirements for the confirmatory test. **The quantity of specimen to be collected should not be defined by SAMHSA but rather by the manufacturers for the use of the specific product – each product /technology requires different amounts.** The amount of sample required for any test is determined by the technologies and / or products being used, not the sample itself, and may be different for screening and confirmation.

For oral fluids, the requirement to collect a 2 mL “neat specimen”, 1.5 mL for the initial test and 0.5 mL for the split specimen, ignores the status of products available for use today. For example, most POCT products only require 0.5 – 1.0 mL of oral fluid for the initial test, but the laboratory would like to have at least 1.0 mL of oral fluid for follow-up confirmation testing. Additionally, the requirement to collect the oral fluid sample in a test tube and then transfer the sample to the POCT eliminates the major benefits of the POCT – simple, non-invasive, sample collection, and no sample handling. It also adds unnecessary cost to the procedure; it requires the addition of a test tube that, in greater than 95% of the tests, will NOT be needed.

Most importantly, based on customer feedback, companies like LifePoint have developed products to meet the market needs for a simple, rapid, accurate product that provides fully integrated sample collection (with no sample handling), sample processing, test analysis and result generation, without any sophisticated user interaction.

LifePoint has developed a saliva collection device for the simple, rapid collection of the split sample for the laboratory confirmation test, and provides that sample, **of known dilution**, in a buffer that stabilizes the sample for transportation to the laboratory. LifePoint has already developed a GC/MS testing protocol with a major reference laboratory that requires less than a 0.5 ml for a confirmation test, leaving an additional 0.5 ml sample for subsequent testing. Although in the introductory background information to the Guidelines you identify the need to collect a 2.0 mL neat oral fluid sample only if the collection device does not provide for an accurate measurement, the proposed Guidelines themselves do not reflect this. The Guidelines need to be changed to allow for oral fluid collection via devices that provide an accurate measurement of the oral fluid

volume for testing by the laboratory.

Lastly, and more importantly, the saliva sample must be preserved in a manner that reduces the rate of degradative processes that may be caused by bacterial contamination or by the enzymes found in saliva, that may significantly alter the sample and jeopardize the accuracy of a confirmation result. **The saliva sample MUST be placed in a buffer or stabilizer of some sort in order to be transported at ambient temperature.** Alternatively, the “neat” oral fluid sample will need to be frozen for transport to the laboratory in order to assure recoverable drug for the confirmation test. The approach proposed by SAMHSA ignores these problems and, more importantly, ignores the tremendous effort made by manufacturers to provide the market, both the employers and the laboratories, with viable alternatives that solve these specimen collection and transport problems.

§3.5 What are the cutoff concentrations for oral fluid specimens?

The proposed guidelines for initially testing drug metabolites and for confirmation testing continues to be technically inconsistent with known drugs and their respective metabolites found in saliva. For saliva, the initial test needs to be performed for the parent drugs, specifically THC parent drug and cocaine (Δ^9 THC and cocaine). Since both of these drugs may metabolize during transport of the sample to the laboratory, the **confirmation test MUST include THC metabolites and cocaine metabolites (benzoylecgonine).**

Minimally, for these analytes, testing should be for the combination of the parent drug (Δ^9 THC and cocaine) and the metabolites (THC metabolites and cocaine metabolites). This will allow for the initial identification of the parent drug for on-site testing, but also allow for confirmation of the metabolites when the parent drug has hydrolyzed during transport to the laboratory. (Cocaine or THC will generally not be found in the confirmation test due to hydrolysis). Additionally, since there are no currently available quality control materials containing stable THC, if both THC and THCA are not tested, then QC and PT testing will be impossible.

Likewise, setting the confirmatory cutoffs for THC Parent Drug is questionable since the THC Parent Drug (Δ^9 THC) will most likely have hydrolyzed by the time a sample reaches a confirmatory laboratory. (Similarly, Cocaine will have hydrolyzed to its metabolites.) Therefore, the confirmatory cutoffs for THC and Cocaine should be for the parent drug *and* metabolites.

Regarding cutoffs, while the limit of drug detection by GC /MS theoretically is as low as 1 ng/mL, the actual limit of sensitivity by most labs for THC is 10 ng/mL – or even higher. This was supported by the data collected by DTAB in the initial pilot proficiency testing program. This means that many laboratories will have difficulty in confirming a positive THC result of less than 10 – 15 ng/mL even though some of the newer technologies exhibit this level of sensitivity on the initial test. On this basis, it would seem logical to set the limit of detection at a

level at least two SD's above the limit of sensitivity, to perhaps 15 ng/mL for THC. Otherwise, valid presumptive positive initial tests could not be confirmed by the laboratory.

LifePoint has now performed a significant number of clinical studies with oral fluid on-site test results compared to GC/MS. Based on the field data obtained to date, we recommend the following cutoffs (ng/mL):

Analyte	Initial Test*	Confirmation*
Amphet/Meth	100	50
Cocaine	Cocaine and BE 20	Cocaine and BE 10
THC	THC and metabolites 15**	THC parent and metabolites 4
Opiates	Morphine 40	Morphine <40** Codeine <40** 6 Acetylmorphine 4
PCP	PCP 20	PCP <10**

* Drug concentrations are expressed in ng/mL

** In setting confirmation cutoff levels for drugs of abuse, it is advisable that these levels be adjusted lower than the corresponding initial screen cutoffs in order to reduce the frequency of false positive results.

§3.9 What validity tests must be performed on an oral fluid sample?

First and foremost, unlike urine, saliva is a 100% observed collection, and the opportunity for adulteration and substitution is negligible. Clearly, a witnessed or observed saliva donation negates the need to give further proof that the specimen is saliva.

If the observation alone is not considered a sufficient deterrent, then a simple waiting period of 10 minutes should be sufficient to ensure that someone does not have something in his or her mouth. It is **almost impossible** to keep a liquid in your mouth for over 5 minutes without swallowing saliva or drooling.

IgG testing at the confirmation stage may be deemed necessary to assure that the sample was stored and transported without interference. For the laboratory or IITF, an IgG does NOT have to be done on a neat oral fluid sample, but can be done on a known dilution of an oral fluid sample that has been sent to the lab. This will allow validity testing even on buffer stabilized samples (provided the dilution is known) for better accuracy and stabilization of the drug in the sample.

An IgG test cannot currently be performed in the field or outside of a laboratory or IITF. The only method currently available is a laboratory- based EIA test; since one is looking at IgG in the µg range. We are more familiar with the testing level being set at 0.5µg/mL rather than the 0.1µg/mL proposed in the Guidelines. The requirement to have this validity test performed at the initial test is a blatant push

toward laboratory-based testing and is onerous and unfair to on-site testing procedures and products.

§3.13 What criteria are used to report an oral fluid sample as adulterated?

Very few direct observations are conducted on urine specimen collections. Why should saliva be held to a higher standard? If you observe the saliva collection, the probability is very high that you are getting a real sample everytime.

Behaviors to adulterate an oral fluid sample have yet to be seen or established. No definition of adulterants for oral fluid have yet been determined. Therefore, at this time, any standards or regulations for testing for adulterants that have yet to be seen or defined at this time are premature.

We strongly recommend that SAMHSA take the same approach that has been successfully used for years with urine-based testing; add additional requirements when adulterants become a known problem.

§3.16 What criteria are used to report an oral fluid specimen as substituted?

Very few direct observations are conducted on urine specimen collections. Why should saliva be held to a higher standard? If you observe the saliva collection, the probability is very high that you are getting a real sample everytime.

If testing for IgG becomes a requirement to determine if an oral fluid sample has been substituted, we are more familiar with the testing level being set at 0.5µg/mL rather than the 0.1µg/mL proposed in the Guidelines. An IgG test cannot currently be performed in the field or outside of a laboratory or IITF. The only method currently available is a laboratory- based EIA test; since one is looking at IgG in the µg range.

Behaviors to substitute an oral fluid sample have yet to be seen or established. No definition of substitution for oral fluid have yet to be determined. Therefore, at this time, any standards or regulations for testing for substitutions that have yet to be seen or defined are premature.

We strongly recommend that SAMHSA take the same approach that has been successfully used for years with urine-based testing; add additional requirements as substitution problems become known.

§4.1 Who may collect a specimen

(c) It is ridiculous to prohibit a collector from linking the donor to the donor test result. For decades, Blood Alcohol Testers (BATs) have been collecting the sample, completing the test and obtaining the results in the presence of the donor without any negative implications or repercussions. This requirement just

adds cost to the process in that two people may be required when one could suffice, and eliminate the most desirable products that integrate the specimen collection, specimen processing, test analysis and result generation, seamlessly as is done in breath alcohol testing.

Although we can understand why it may be desirable to prevent the donor to have un-controlled access to a test device, there are many reasons why an integrated collection and test unit is highly desirable, and will improve the overall accuracy and efficiency of the testing process.

One of the biggest sources of error in laboratory testing is the sample mis-identification or results mix-up. The use of an integrated system that collects, tests, and provides an instrumented results with no possibility of either a mix-up in specimens or test results will have a significant positive impact on improved accuracy for the total testing system. In most cases, the test device itself is a closed unit, and even if the person had access to it, it cannot be tampered with without evidence of tampering. Additionally, integrated collection, processing, and results have been used for years very positively in the breath alcohol testing mode.

Lastly, no sample handling is one of the requirements for a product to be CLIA waived, which means that it improves the level of accuracy and eliminates one of the major sources of errors in testing by non-laboratory personnel.

In addition, in the case of the integrated test cups, such as those offered by Roche or Dade Behring, the test strips are isolated and sealed in a part of the cup where the donor cannot touch or interfere with the test strips. Our concern is that by requiring the collector to use a separate collection cup, an unnecessary step is being required. The donor should be able to void right into the test cup.

With an oral fluid integration collection and test device for POCT, it is impractical to not have the donor be present and hold the device. Why not require observed collection instead for oral fluid products. This is the best scenario for oral fluid.

For oral fluid sampling, we strongly recommend that the wording be modified to allow the oral fluid specimen to be collected by the collector and/or the POCT tester directly into an appropriate container and/or testing device. Saliva/ oral fluid is very difficult to aliquot. Based on customer feedback, the ideal product provides a completely automated and fully integrated sample collection, processing, test analysis and result generation without any additional sample handling or operator interface. This is the same approach that has been used for decades by breath alcohol testers; the sample, breath, is collected and tested immediately - there is no separate collector and no separate tester.

We also strongly object to the SAMHSA proposed requirement that the donor NOT observe the test being conducted. The US Postal Service provided testimony at a previous DTAB meeting indicating that they have done over 50,000 on-site tests and have had NO complaints or problems with the testing being done with the donor present. Nearly 6 years later there is no evidence of

confrontations. In fact, the US Postal Service and the United Transportation Union testified that they -that the sample tested is theirs and that a mix-up of specimens has not occurred.

We strongly recommend that the wording be revised as follows: "For oral fluid, the sample is provided into the appropriate container or collection device by the donor under the direct observation of the collector/tester. Only the collector/tester may be present while the donor provide the sample and perform the test."

We recommend that for oral fluid sampling, the wording be modified to allow assistance by the collector if the donor is having difficulty producing a specimen or if the donor is in some way incapacitated or unable to perform the collection. The fact that the collector will have significant more experience in the collection process will facilitate the collection if allowed to assist. We can think of no reason that this should not be allowed, for example, the collector applies the sweat patch.

We recommend that the wording be "For oral fluid, the collection device must be inserted into and removed from the donor's mouth by either the donor or the collector."

§4.2 and 4.3

We support the training and certification of POCT testers, but not collectors. We continue to question why certification of collectors is required; there does not seem to be a significant problem with inappropriate collections. Either manufacturers of the collection devices, or laboratories using the devices to collect and transport the specimens for testing can provide the training themselves, or they can appoint trainers who can do the training. This requirement will add a significant amount of additional cost to the testing process and appears to be unnecessary. What is the government's justification in requiring this?

Minimally, one should require that a certification to perform on-site testing include collection procedures and thereby eliminates the need for double certification.

§5.6 What are the privacy requirements when collecting an oral fluid specimen?

For oral fluid sampling, we strongly recommend that the wording be modified to allow the oral fluid specimen to be collected by the collector and/or the POCT tester directly into an appropriate container and/or testing device. Saliva/ oral fluid is very difficult to aliquot. Based on customer feedback, the ideal product provides a completely automated and fully integrated sample collection, processing, test analysis and result generation without any additional sample handling or operator interface. This is the same approach that has been used for

decades by breath alcohol testers; the sample, breath, is collected and tested immediately - there is no separate collector and no separate tester.

Although we can understand why it may be desirable to prevent the donor to have un-controlled access to a test device or be present when the test is performed, there are many reasons why an integrated collection and test unit is highly desirable, and will improve the overall accuracy and efficiency of the testing process.

One of the biggest sources of error in laboratory testing is the sample mis-identification or results mix-up. The use of an integrated system that collects, tests, and provides an instrumented results with no possibility of either a mix-up in specimens or test results will have a significant positive impact on improved accuracy for the total testing system. In most cases, the test device itself is a closed unit, and even if the person had access to it, it cannot be tampered with without evidence of tampering. Additionally, integrated collection, processing, and results have been used for years very positively in the breath alcohol-testing mode.

Lastly, no sample handling is one of the requirements for a product to be CLIA waived, which means that it improves the level of accuracy and eliminates one of the major sources of errors in testing by non-laboratory personnel.

In addition, in the case of the integrated test cups, such as those offered by Roche or Dade Behring, the test strips are isolated and sealed in a part of the cup where the donor cannot touch or interfere with the test strips. Our concern is that by requiring the collector to use a separate collection cup, an unnecessary step is being required. The donor should be able to void right into the test cup.

With an oral fluid integration collection and test device for POCT, it is impractical to not have the donor be present and hold the device. Why not require observed collection instead for oral fluid products. This is the best scenario for oral fluid.

We recommend that the requirement that the donor must not have access to the test device be eliminated when the device has a tamper-proof design and/or the donor does not have un-controlled access to the test device (the tester is present when the collector/test device is being used and/or the donor does not touch the test device as would occur in saliva testing).

We strongly object to the SAMHSA proposed requirement that the donor NOT observe the test being conducted. The US Postal Service provided testimony at a previous DTAB meeting indicating that they have done over 50,000 on-site tests and have had NO complaints or problems with the testing being done with the donor present. Nearly 6 years later there is no evidence of confrontations. In fact, the US Postal Service and the United Transportation Union testified that they -that the sample tested is theirs and that a mix-up of specimens has not occurred.

We strongly recommend that the wording be revised as follows: "For oral fluid,

the sample is provided into the appropriate container or collection device by the donor under the direct observation of the collector/tester. Only the collector/tester may be present while the donor provides the sample and performs the test.”

We recommend that for oral fluid sampling, the wording be modified to allow assistance by the collector if the donor is having difficulty producing a specimen or if the donor is in some way incapacitated or unable to perform the collection. The fact that the collector will have significant more experience in the collection process will facilitate the collection if allowed to assist. We can think of no reason that this should not be allowed, for example, the collector applies the sweat patch.

We recommend that the wording be “For oral fluid, the collection device must be inserted into and removed from the donor’s mouth by either the donor or the collector.”

§ 7.1 What is a collection device?

(c)The recommendation to use only a single use plastic specimen container may not provide a valid sample to the laboratory. The saliva sample must be preserved in some way in order to reduce the rate of degradative processes that may be caused by bacterial contamination or by the enzymes found in saliva, that may significantly alter the sample and jeopardize the accuracy of a confirmation result. **The saliva sample MUST be placed in a buffer or stabilizer of some sort in order to be transported at ambient temperature.** Alternatively, the “neat” oral fluid sample will need to be frozen for transport to the laboratory in order to assure recoverable drug for the confirmation test. The approach proposed by SAMHSA ignores these problems and, more importantly, ignores the tremendous effort made by manufacturers to provide the market, both the employers and the laboratories, with viable alternatives that solve these specimen collection and transport problems.

There is a scientific reason why the development of saliva collection devices by manufacturers has been so arduous. The use of 1) collection/test devices for the initial test, and 2) saliva collection/ transport containers **MUST** be allowed if the laboratory expects to be able to perform a valid test. These saliva collection products, both for the initial test and for collection of a second sample to send to the laboratory have already been developed and validated for use according to the manufacturers instructions.

Although in the introductory background information you identify the need to collect a 2.0 mL neat oral fluid sample only if the collection device does not provide for an accurate measurement, the Guidelines themselves do not reflect this. The Guidelines need to be changed to allow for oral fluid collection via devices that provide an accurate measurement of the oral fluid for testing by the laboratory.

§ 8.3 What procedure is used to collect an oral fluid specimen?

Although in the introductory background information you identify the need to collect a 2.0 mL neat oral fluid sample **only if the collection device does not provide for an accurate measurement**, the Guidelines themselves do not reflect this. The Guidelines need to be changed to allow for oral fluid collection via devices that provide an accurate measurement of the oral fluid for testing by the laboratory in addition to the stipulation of a 2.0 mL neat oral fluid sample if the collection device does not give an accurate measurement.

Additionally, for oral fluid sampling, we strongly recommend that the wording be modified to allow the oral fluid specimen to be collected by the collector and/or the POCT tester directly into an appropriate container and/or testing device. Saliva is very difficult to aliquot outside of a laboratory environment. More importantly, because of the potential for delay during the expectoration process (which can take 15 – 20 minutes), you may get partitioning of some drugs in saliva. If the expectorated sample is not vigorously mixed (as vortexing) after collection but before splitting the oral fluid specimen, one may get significantly different results for the two aliquots.

Based on user feedback, the ideal product provides a completely automated and fully integrated sample collection, processing, test analysis and result generation without any additional sample handling or operator interface. **For decades, Blood Alcohol Testers (BATs) have been collecting the sample, completing the test and obtaining the result with the donor present with no negative results or implications.** There is no reason that the same approach cannot be used for drug testing. This proposed requirement just adds cost to the testing process in that two people may be required to sample and test when one person could do both.

We do not have a problem with the donor observing the test being conducted and this is routinely done in alcohol testing. This appears to be an unnecessary requirement; what's the government's justification?

The US Postal Service provided testimony at the September 2001 DTAB meeting indicating that they have performed over 50,000 on-site tests and have had **NO** complaints or problems with the testing being done in the presence of the donor. Nearly 4 years later there is no evidence of confrontations. In fact, the US Postal Service and the United Transportation Union testified that they prefer the testing be done with the donor present, since they can then be certain that the sample tested is theirs and that a mix-up of specimens has not occurred.

Additionally, the alcohol testing programs have been performing tests with the donor present for years and have also not had a problem. Lastly, this requirement WILL cause a problem with integrated devices—which has been one of the “want to have” features of products, since it eliminates the possibility of misidentification and the need for COC. Many studies have shown that one of

the biggest sources of error in laboratory testing is the sample mis-identification or results mix-up. Studies have shown this error rate to be an average of 5% in laboratory testing. By using an integrated system that collects, tests, and provides an instrumented result with no possibility of either a mix-up in specimens or test results will have a significant positive impact on improved accuracy for the total testing system. The incorporation of a fully integrated collection, testing, reporting system can actually do more to improve accuracy than a better test method.

The basis for this requirement remains elusive. The presence or absence of the donor could be left up to the employer, since it may resolve some union based objections to drug testing programs.

For oral fluids, the requirement to collect a 2 mL “neat specimen”, 1.5 mL for the initial test and 0.5 mL for the split specimen, ignores the status of products available for use today. For example, most POCT products only require 0.5 – 1.0 mL of oral fluid for the initial test, but the laboratory would like to have at least 1.0 mL of oral fluid for follow-up confirmation testing. Additionally, the requirement to collect the oral fluid sample in a test tube and then transfer the sample to the POCT eliminates the major benefits of the POCT – simple, non-invasive, sample collection, and no sample handling. It also adds unnecessary cost to the procedure since you are now requiring the addition of a test tube that, in greater than 95% of the tests, will NOT be needed. Lastly, it will significantly increase the amount of time needed for the collection process itself. Many products do not require 2.0 mL of oral fluid, but significantly less oral fluid; therefore, the requirement for an unnecessary 2.0 mL of specimen will significantly increase the amount of time the collector and donor need to be available to complete the collection. It also ignores SAMHSA’s own definition of split sample which allows for near simultaneously collected specimens. We strongly recommend the use of a POCT testing device BEFORE the requirement to collect the split sample. To require otherwise is onerous and adds unnecessary cost and time to the process.

We recommend the Guidelines be modified as follows:

(6) Under direct observation, the collector/tester will give the donor a clean specimen tube, or if the collection device provides an exact measurement, the appropriate collection/test device. If the collection is into a plastic specimen tube, the collection can occur over a 15 minute time period or until the appropriate volume of the specimen is collected.

(7) Both the donor and the collector must keep the sampling/testing device in view at all times prior to the tube being sealed or the POCT test being completed. If the test result is positive, a split sample is then collected as in (6) above. The appropriate sampling device is then labeled.

(8) Etc. through (16)

(17) If a plastic specimen tube has been used, or if the POCT test is not integrated into the specimen collection and process, the specimen is sent to the(etc)

We recommend that for oral fluid sampling, the wording be modified to allow assistance by the collector if the donor is having difficulty producing a specimen or if the donor is in some way incapacitated or unable to perform the collection. The fact that the collector will have significant more experience in the collection process will facilitate the collection if allowed to assist. We can think of no reason that this should not be allowed, for example, the collector applies the sweat patch.

We recommend that the wording be "For oral fluid, the collection device must be inserted into and removed from the donor's mouth by either the donor or the collector."

§ 9.7 What are the PT requirements for an applicant laboratory to conduct oral fluid testing?

External proficiency testing will undoubtedly be introduced into the testing regime at some point in the future. It will not be dissimilar to current practices in the clinical laboratory, the CAP program, which consists of running controls at two levels twice per year. However, a lot of work needs to be done on oral fluids to get to that stage in order to understand the choice of matrix, the drugs/metabolites to be spiked, method biases and, particularly in the case of pad adsorption methods, the relative loss of drugs by irreversible binding.

Since it is very probable that different products and technologies will provide significantly different results because of the influence of the PT matrix on the testing process and result, we strongly recommend the use of a multi-site, consensus approach to PT testing with reference ranges provided for each type of technology, product and process.

Additionally, since behaviors to adulterate or substitute an oral fluid sample have yet to be seen or established, and no definition of substitution or adulteration for oral fluid has yet to be determined, any PT testing for adulterants, etc. is premature.

We strongly recommend that SAMHSA take the same approach that has been successfully used for years with urine-based testing; add additional requirements to a PT program as adulterants and substitution problems become known.

§ 9.11 What are the PT requirements for an HHS certified laboratory to conduct oral fluid testing?

External proficiency testing will undoubtedly be introduced into the testing regime

at some point in the future. It will not be dissimilar to current practices in the clinical laboratory, the CAP program, which consists of running controls at two levels twice per year. However, a lot of work needs to be done on oral fluids to get to that stage in order to understand the choice of matrix, the drugs/metabolites to be spiked, method biases and, particularly in the case of pad adsorption methods, the relative loss of drugs by irreversible binding.

Since it is very probable that different products and technologies will provide significantly different results because of the influence of the PT matrix on the testing process and result, we strongly recommend the use of a multi-site, consensus approach to PT testing with reference ranges provided for each type of technology, product and process.

Additionally, since behaviors to adulterate or substitute an oral fluid sample have yet to be seen or established, and no definition of substitution or adulteration for oral fluid has yet to be determined, any PT testing for adulterants, etc. is premature.

We strongly recommend that SAMHSA take the same approach that has been successfully used for years with urine-based testing; add additional requirements to a PT program as adulterants and substitution problems become known.

§ 9.15 What are the PT requirements for an applicant IITF to conduct oral fluid testing?

External proficiency testing will undoubtedly be introduced into the testing regime at some point in the future. It will not be dissimilar to current practices in the clinical laboratory, the CAP program, which consists of running controls at two levels twice per year. However, a lot of work needs to be done on oral fluids to get to that stage in order to understand the choice of matrix, the drugs/metabolites to be spiked, method biases and, particularly in the case of pad adsorption methods, the relative loss of drugs by irreversible binding.

Since it is very probable that different products and technologies will provide significantly different results because of the influence of the PT matrix on the testing process and result, we strongly recommend the use of a multi-site, consensus approach to PT testing with reference ranges provided for each type of technology, product and process.

Additionally, since behaviors to adulterate or substitute an oral fluid sample have yet to be seen or established, and no definition of substitution or adulteration for oral fluid has yet to be determined, any PT testing for adulterants, etc. is premature.

We strongly recommend that SAMHSA take the same approach that has been successfully used for years with urine-based testing; add additional requirements to a PT program as adulterants and substitution problems become known.

§ 9.19 What are the PT requirements for a HHS certified IITF to conduct oral fluid testing?

External proficiency testing will undoubtedly be introduced into the testing regime at some point in the future. It will not be dissimilar to current practices in the clinical laboratory, the CAP program, which consists of running controls at two levels twice per year. However, a lot of work needs to be done on oral fluids to get to that stage in order to understand the choice of matrix, the drugs/metabolites to be spiked, method biases and, particularly in the case of pad adsorption methods, the relative loss of drugs by irreversible binding.

Since it is very probable that different products and technologies will provide significantly different results because of the influence of the PT matrix on the testing process and result, we strongly recommend the use of a multi-site, consensus approach to PT testing with reference ranges provided for each type of technology, product and process.

Additionally, since behaviors to adulterate or substitute an oral fluid sample have yet to be seen or established, and no definition of substitution or adulteration for oral fluid has yet to be determined, any PT testing for adulterants, etc. is premature.

We strongly recommend that SAMHSA take the same approach that has been successfully used for years with urine-based testing; add additional requirements to a PT program as adulterants and substitution problems become known.

§ 11.27 What are the requirements for an HHS-certified laboratory to report an oral fluid test result?

(c) For the technical reasons previously cited, there is no technical reason to require that a THC positive oral fluid sample be tested for urine. Data shows that it is not possible to have an oral fluid positive from contamination. This requirement is onerous and blatantly unfair to oral fluid testing. An oral fluid sample that is positive for THC by both the initial test and the confirmatory test should be reported as positive.

§ 12.2 What POCT devices may be used in a Federal Workplace Drug Testing Program?

(a)1

We support the requirement for an FDA-clearance as an efficient way to ensure that only quality products are used for testing. Alternatively, a *new* Conforming Products List could be developed; however, there must be a process to support a 30-day review, followed by a listing within 30 days after approval. This means that inclusion on the List should take no longer than 60 days after submission.

There are many questions that remain unanswered, including who will do the testing?, what are the requirements?, etc. (SAMHSA does not appear to have the resources or the appropriate representatives to accomplish this task.)

The proposed requirement for a second set of product approvals under HHS guidance is a clear example of government redundancy and over-regulation and is onerous and unfair to industry. Does SAMHSA believe that the FDA product approval process is inadequate? Just as SAMHSA would like the FDA to defer to its regulations and guidance on the drug testing *process*, we recommend that SAMHSA defer to the well-established (over 40 years) and accepted FDA product approval process.

More importantly, the way these SAMHSA proposed guidelines and the Draft FDA proposed guidelines are written, show **significant incompatibilities** in the requirements. For example, FDA calls a screen positive a "Presumptive Positive", while this SAMHSA guideline call a screen positive a "Non Negative". How can a POCT, a IITF or a laboratory meet both requirements at the same time – call it a Non Negative Presumptive Positive? This will really confuse everyone and makes it impossible for testing sites, manufacturers, and laboratories to comply. This is only one example of many conflicts in the two guidelines.

Additionally, Breath Alcohol Testing has been used for Federal Workplace Safety Testing for decades and most of these products are NOT FDA cleared.

LifePoint does NOT support the requirement for BOTH FDA clearance and a new Conforming Products List under any circumstances. The requirement for both is onerous and costly to the workplace testing product manufacturers and ultimately workplace testing programs, overall, and is a clear example of onerous, burdensome redundancy in government regulation.

§ 12.6 What criteria will the Secretary use to place a POCT device on the list of SAMHSA-certified POCTs?

(a)(1)The POCT should have the same requirements as a laboratory and only have to pass 80% of the challenges over 3 testing cycles. How can the POCT be held to a higher standard than the laboratory?

(a)(2)The POCT should have the same requirements as a laboratory and only have to pass 50% of the totals drug challenges for an individual drug. How can the POCT be held to a higher standard than the laboratory?

(a)(3) and (a)(4) The POCT should have the same requirements as a laboratory and only have to pass 80% of the challenges for each validity sample over 3 testing cycles. How can the POCT be held to a higher standard than the laboratory?

Additionally, the specified validity test for oral fluid is an IgG test. An IgG test cannot currently be performed on any POCT device or in the field or outside of a laboratory or IITF. The only method currently available is a laboratory-based EIA test; since one is looking at IgG in the μg range. We are more familiar with the testing level being set at $0.5\mu\text{g/mL}$ rather than the $0.1\mu\text{g/mL}$ proposed in the Guidelines. Therefore, the requirement to have the IgG validity test required for an oral fluid device is a blatant push toward laboratory-based testing and is onerous and unfair to oral fluid POCT devices.

(a)(5) Behaviors to adulterate an oral fluid sample have yet to be seen or established. No definition of adulterants for oral fluid has yet to be determined. Therefore, any standards or regulations for testing for adulterants that have yet to be seen or defined at this time are premature.

We strongly recommend that SAMHSA take the same approach that has been successfully used for years with urine-based testing; add additional requirements as adulterants become a known problem.

(b) External proficiency testing will undoubtedly be introduced into the testing regime at some point in the future. It will not be dissimilar to current practices in the clinical laboratory, the CAP program, which consists of running controls at two levels twice per year. However, a lot of work needs to be done on oral fluids to get to that stage in order to understand the choice of matrix, the drugs/metabolites to be spiked, method biases and, particularly in the case of pad adsorption methods, the relative loss of drugs by irreversible binding.

Since it is very probable that different products and technologies will provide significantly different results because of the influence of the PT matrix on the testing process and result, we strongly recommend the use of a multi-site, consensus approach to PT testing with reference ranges provided for each type of technology, product and process.

Therefore, to make the use of a yet-to-be-determined oral fluid PT program a requirement for a POCT oral fluid device to be placed on the "list" is onerous and unfair.

§ 12.7 What is required for a FDA cleared POCT device to continue on the list of SAMHSA-certified devices?

(b) Again it is onerous and adds unnecessary cost to the entire process to require annual product validation. FDA cleared products for decades have not had to do so. Federally validated Breath Alcohol Tests do not have to submit to annual validations. Why then is SAMHSA proposing this ridiculous requirement? Once a product has been approved, either by FDA or SAMHSA (but NOT both), the reporting of problems should be the only reason for HHS to require a re-look at a specific product.

§ 12.8 What are the responsibilities of a Federal agency that wished to conduct POCT?

(f) The requirement for quarterly PT testing for POCT is overly onerous and unfair. The laboratories and IITF only require three tests per year. The CAP program that is used to certification for hospital laboratories is only twice per year. The same timing requirements that apply to laboratories should also apply to POCT sites.

(k) The requirement to IMMEDIATELY suspend use of any POCT device where there is any failure of any PT is blatantly unfair and overly onerous. A similar failure by a laboratory of IITF gives the laboratory of IITF 5 or 30 days to respond to and cure the deficiency. (see section 9.23) The same ability to respond and cure should apply to the POCT manufacturer or testing site – there are many reasons for PT failure that do not relate to the performance of the testing site or the POCT device, and the testing site and the POCT device should be given the same appropriate amount of time to address the potential deficiency.

§ 12.9 What are the qualitative and quantitative specifications for PT samples that are used to evaluate test devices submitted by manufacturers or for a Federal Agency to evaluate a POCT site and tester?

External proficiency testing will undoubtedly be introduced into the testing regime at some point in the future. It will not be dissimilar to current practices in the clinical laboratory, the CAP program, which consists of running controls at two levels twice per year. However, a lot of work needs to be done on oral fluids to get to that stage in order to understand the choice of matrix, the drugs/metabolites to be spiked, method biases and, particularly in the case of pad adsorption methods, the relative loss of drugs by irreversible binding.

Since it is very probable that different products and technologies will provide significantly different results because of the influence of the PT matrix on the testing process and result, we strongly recommend the use of a multi-site, consensus approach to PT testing with normal ranges provided for each type of technology, product and process.

Therefore, to make the use of a yet-to-be-determined oral fluid PT program a requirement for a POCT oral fluid device to be placed on the “list” is onerous and unfair.

(b) 50 % above cut-off is an acceptable level for a positive while a negative should be just that i.e. negative. To have more stringent standards, especially for oral fluids (see above) is again onerous and unfair to oral fluid POCT devices.

Previously, these 25% requirements had been acceptable to urine testing because you are testing at fairly high cutoffs. But with the addition of alternate

specimens, the cutoff levels in many areas are now much lower than previously used. For example, if the cutoff for urine is 50 ng/mL, then 25% above the cutoff is 62.5 ng/mL; and an acceptable answer anything within a 12.5 ng/mL range; this is well within the capabilities of the urine testing products. However, at the very low level being discussed for oral fluids, (THC is 4 ng/mL), 25% above this is 5 ng/mL and an acceptable answer is only a result within 1 ng/mL range. This level of performance is very difficult even for lab-based instrumented systems to achieve.

(d) Behaviors to adulterate or substitute or add interfering substances to an oral fluid specimen have yet to be seen or established, and definitions have yet to be determined. Therefore, any standards or regulations for testing for these substances, which have yet to be seen in use or defined, are premature.

We strongly recommend that SAMHSA take the same approach that has been successfully used for years with urine-based testing; add additional requirements as adulterants become a known problem.

(i) Additionally, the specified validity test for oral fluid is an IgG test. An IgG test cannot currently be performed on any POCT device or in the field or outside of a laboratory or IITF. The only method currently available is a laboratory- based EIA test; since one is looking at IgG in the μg range. We are more familiar with the testing level being set at $0.5\mu\text{g/mL}$ rather than the $0.1\mu\text{g/mL}$ proposed in the Guidelines. Therefore, the requirement to have the IgG validity test required for an oral fluid device is a blatantly unfair and onerous requirement for POCT devices.

§ 12.12 What is a failure for the purposes of a POCT?

Again, there is a significantly bias against POCT testing. The definition of a failure is much more stringent for a POCT device than the definition of a failure for a laboratory or an IITF. Laboratories or an IITF must only pass 80% of the PT drug challenges over two testing cycles (section 9.19), while ANY failure by a POCT is immediate. Again this is blatantly unfair and onerous. The POCT should have the same requirements as a laboratory and only have to pass 80% of the PT challenges over 2 testing cycles. How can the POCT be held to a higher standard than the laboratory?

§ 12.13 What is the responsibility of the Secretary when a failure is reported?

The requirement to IMMEDIATELY suspend use of any POCT device and remove it from the product list where there is any failure of any PT is blatantly unfair and overly onerous. A similar failure by a laboratory of IITF gives the laboratory of IITF 5 or 30 days to respond to and cure the deficiency BEFORE the Secretary takes any action. (see section 9.26) The same ability to respond and cure should apply to the POCT manufacturer or testing site **before** any

action is taken. Only if there is no explanation or cure should there be any action taken, as is outlined for laboratories and IITF sites; the POCT device should be given the same appropriate amount of time to explain or cure the potential deficiency.

However, unlike laboratory processes, fixing a product problem is not quick and 30 days is an unreasonably short period of time to complete a corrective action, depending on the nature of the problem. We recommend that this be revised to 60 days.

Additionally, we again object to the requirement to notify the FDA. Duplicative regulation is unnecessarily burdensome and onerous. Additionally, the FDA already has reporting procedures for product failures if this market becomes regulated by FDA.

§ 12.18 What are the requirements for conducting a POCT?

We do not have a problem with the donor observing the test being conducted and this is routinely done in alcohol testing. This appears to be an unnecessary requirement; what's the government's justification?

Although we can understand why it may be desirable to not allow the donor to have un-controlled access to a test device, there are many reasons why an integrated collection and test unit is highly desirable, and will improve the overall accuracy and efficiency of the testing process.

One of the biggest sources of error in laboratory testing is the sample mis-identification or results mix-up. The use of an integrated system that collects, tests, and provides an instrumented results with no possibility of either a mix-up in specimens or test results will have a significant positive impact on improved accuracy for the total testing system. In most cases, the test device itself is a closed unit, and even if the person had access to it, it cannot be tampered with without evidence of tampering. Additionally, integrated collection, processing, and results have been used for years very positively in the breath alcohol-testing mode.

Lastly, no sample handling is one of the requirements for a product to be CLIA waived, which means that it improves the level of accuracy and eliminates one of the major sources of errors in testing by non-laboratory personnel.

In addition, in the case of the integrated test cups, such as those offered by Roche or Dade Behring, the test strips are isolated and sealed in a part of the cup where the donor cannot touch or interfere with the test strips. Our concern is that by requiring the collector to use a separate collection cup, an unnecessary step is being required. The donor should be able to void right into the test cup.

With an oral fluid integration collection and test device for POCT, it is impractical to not have the donor be present and hold the device. Why not require observed

collection instead for oral fluid products. This is the best scenario for oral fluid.

We recommend that the requirement that the donor must not have access to the test device be eliminated when the device has a tamper-proof design and/or the donor does not have un-controlled access to the test device (the tester is present when the collector/test device is being used and/or the donor does not touch the test device as would occur in saliva testing).

We strongly object to the SAMHSA proposed requirement that the donor NOT observe the test being conducted. The US Postal Service provided testimony at a previous DTAB meeting indicating that they have done over 50,000 on-site tests and have had NO complaints or problems with the testing being done with the donor present. Nearly 6 years later there is no evidence of confrontations. In fact, the US Postal Service and the United Transportation Union testified that they -that the sample tested is theirs and that a mix-up of specimens has not occurred.

The basis for this requirement remains elusive. The presence or absence of the donor could be left up to the employer, since it may resolve some union based objections to drug testing programs.

We recommend that for oral fluid sampling, the wording be modified to allow assistance by the collector if the donor is having difficulty producing a specimen or if the donor is in some way incapacitated or unable to perform the collection. The fact that the collector will have significant more experience in the collection process will facilitate the collection if allowed to assist. We can think of no reason that this should not be allowed, for example, the collector applies the sweat patch.

(b) The requirement that the specimen collector and POCT tester be different people is onerous and unnecessary. For oral fluid sampling, we strongly recommend that the wording be modified to allow the oral fluid specimen to be collected by the collector and/or the POCT tester; the donor can still leave the room before the test result is available. Based on user feedback, the ideal product provides a completely automated and fully integrated sample collection, processing, test analysis and result generation without any additional sample handling or operator interface. For decades, Blood Alcohol Testers (BATs) have been collecting the sample, completing the test and obtaining the result with the donor present with no negative results or implications. There is no reason that the same approach cannot be used for drug testing. This proposed requirement to separate these two tasks and the requirement for two different people just adds cost to the testing process in that two people may be required to sample and test when one person could do both.

(e) The requirement for a urine sample to be sent to the laboratory in conjunction with the saliva sample is again unfair and unnecessary. We refer you to the technical data provided above as to the incorrect statement and inappropriate concern about possible oral fluid contamination for THC positive results.

§ 12.19 What are the quality control requirements when conducting POCTs?

This QC section cannot be strengthened enough to satisfy some industry experts. This requirement WILL add cost, necessitate additional training, and subject the process to error and/or noncompliance. It will virtually eliminate the use of on-site testing by smaller companies that cannot incur the additional cost of maintaining positive and negative controls. Even large volume testers, who are currently flocking to on-site testing to take advantage of its cost-effectiveness, may be inclined to shy away from on-site testing in particular – or discontinue drug testing all together.

First and foremost, QC procedures should be developed and validated by each manufacturer for each specific instrument or product to warrant that each test system is in control and thereby provides reliable results. The frequency and type of QC procedures are specific to each product, and are best developed by each manufacturer. These product procedures should not be determined by SAMHSA.

Additionally, since SAMHSA is now requiring FDA approval of all products, the **FDA clearance process requires that the manufacturer support the validity of these QC procedures as part of the product approval process**, with product specific recommendations included in the package insert.

Particularly troubling is that this QC section, as well as others, presumes a relationship between the end-user and a laboratory. A major benefit of on-site testing is the elimination of the laboratory in the testing process for negative specimens. Yet according to § 12.13 (c), DTAB would have one out of every ten negative specimens submitted to a HHS-certified laboratory as part of the Quality Assurance Program. As a result, virtually every company that conducts on-site testing and wishes to abide by the mandatory guidelines will have to add a laboratory test for approximately 15% of the test specimens rather than only about 5% for confirmation of positives, thus eliminating one of the benefits of on-site testing -- reduced lab costs. It will also add cost and administrative burden that will discourage on-site testing.

Excessive QC testing was one of the major reasons that a lot of physician office testing was eliminated with the introduction of CLIA - it significantly increased the cost of the test. If the goal is to improve the testing efficiency and efficacy of the drug testing process, a more cost-effective approach needs to be identified.

We support the concept of running QC samples; however, almost all of the on-site test devices have internal controls that indicate when an assay is not performing. Because of this the FDA has developed and currently uses a cost-effective and efficient QC protocol for easy-to-use on-site products (CLIA-waived products) similar to those being used in drug test:

- 1) once a month,
- 2) each new shipment,
- 3) each new lot, and
- 4) whenever problems are identified.

We recommend that a positive and negative control be run as is currently supported by the FDA as shown above, in its clearance of similar products (as long as the POCT location has used and stored the product according to the manufacturer's directions). This approach ensures the ongoing integrity of the testing system without imposing significant unnecessary financial constraints on the POCT location or employer.

Running a negative and a positive control each day is both costly and unnecessary. See the paragraph above for recommendations that will maintain the integrity of the testing process while keeping it cost effective for testing sites with lower test volumes.

LifePoint recommends that for PT and QC, the ranges used to challenge the system be set at $\pm 50\%$; this would allow all current on-site technologies and analytes being tested at low levels to meet the standards.

Previously, these 25% requirements had been acceptable to urine testing because you are testing at fairly high cutoffs. But with the addition of alternate specimens, the cutoff levels in many areas are now much lower than previously used. For example, if the cutoff for urine is 50 ng/mL, then 25% above the cutoff is 62.5 ng/mL; and an acceptable answer anything within a 12.5 ng/mL range; this is well within the capabilities of the urine testing products. However, at the very low level being discussed for oral fluids, (THC is 4 ng/mL), 25% above this is 5 ng/mL and an acceptable answer is only a result within 1 ng/mL range. This level of performance is very difficult even for lab-based instrumented systems to achieve.

(a)1 and (a)2

First and foremost, QC procedures should be developed and validated by each manufacturer for each specific instrument or product to warrant that each test system is in control and thereby provides reliable results. The frequency and type of QC procedures are specific to each product, and are best developed by each manufacturer. These product procedures should not be determined by SAMHSA.

Additionally, since SAMHSA is now requiring FDA approval of all products, the FDA clearance process requires that the manufacturer support the validity of these QC procedures as part of the product approval process, with product specific recommendations included in the package insert. For example, most POCT devices have built in quality control reagents and additional QC testing is often not required. We strongly recommend that the regulations require the

testing site to abide by the FDA cleared manufacturer recommendations.

Lastly, the proposed quality control requirements section reflect laboratory-type QC testing where quality control is needed for liquid reagent, batch-type tests often performed by a laboratory (who are often making their own reagents or diluting the manufacturer reagents – which do not have FDA approval). There are no “batches” in unit type testing and there is no possibility of carryover in non-batch testing. Additionally, this level of control is excessive for unit type tests where the manufacturer has already completed more extensive testing than a laboratory ever does to ensure the integrity of the test. These procedures might be better labeled “batch testing quality control requirements” since this is where they apply – not single unit tests that may be initial tests.

(c)

We recommend that the QC requirements for a laboratory be as rigorous or more rigorous than an initial test in an IITF or POCT. The requirement for re-testing 10% of the negatives should also be applied to the initial test done in a laboratory. Again, applying this standard to a POCT sites but not to a laboratory or IITF site shows a bias against POCT testing. Many of the products that will be used in the POCT and/or IITF provide the same automated level of QC as is being required at the laboratory, but the laboratory does not have the additional standard for re-testing 10% of the negatives. This is onerous and unfair to the on-site test methods and holds the POCT test to a higher standard than the laboratory.

§ 12.21 What does a POCT tester do with a specimen after conducting a POCT?

(b) The requirement for sending 10% of the POCT negatives for confirmation is unfair. If there is a real concern about false negative results, then the same requirement should also be applied to the initial test done in a laboratory or an IITF.. Again, applying this standard to a POCT testing but not to a laboratory or IITF site shows a bias against POCT testing. Many of the products that will be used in the POCT and/or IITF provide the same level of accuracy as is being delivered by a laboratory or IITF, but the laboratory or IITF does not have the additional standard for re-testing 10% of the negatives. This is onerous and unfair to the on-site test methods.

§ 12.22 How is a POCT negative result reported?

This is one of the most burdensome and unnecessary requirements relative to the entire drug testing process found in these guidelines. There is no legitimate, functional reason to have MROs review negative results. The fact that this section allows up to 3 working days to transmit such results to MROs is evidence of the requirement’s utter wastefulness. For what possible purpose would an employer need to have an MRO review a 3-day old negative test result? There is none and yet this would add significant cost burden to the employer –

especially in light of the fact that 96% of the tests completed are negative (Quest published data, 2000). This should not be dictated by SAMHSA but be the employer's choice.

This requirement will add cost to each on-site test but bring with it virtually no value or benefit. It will also add administrative burden that may discourage employers from either using on-site testing at all or doing so without the additional expense of having a third-party manage the process (TPA).

§ 15.4 How does and HHS-certified laboratory test a split oral fluid specimen for adulterants when the primary specimen was reported as adulterated?

Behaviors to adulterate an oral fluid sample have yet to be seen or established. No definition of adulterants for oral fluid has yet to be determined. Therefore, any standards or regulations for testing for adulterants that have yet to be seen or defined at this time are premature.

We strongly recommend that SAMHSA take the same approach that has been successfully used for years with urine-based testing; add additional requirements as adulterants become a known problem.

§ 17 Subpart Q Laboratory or IITF suspension /Revocation Procedures

The inclusion of due process for the donor, the tester, the laboratory and the IITF are all well documented in these guidelines. However, even though SAMHSA is now proposing to regulate POCT products, throughout this document there is NO due process for the manufacturer. This is blatantly unfair. If SAMHSA is going to begin to regulate POCT products (in addition to FDA), then SAMHSA must make these same due process procedures apply to all.

Exhibit A

LifePoint, Inc. has developed and is now marketing a unique product – the first non-invasive, on-site testing system that will deliver blood-comparable results without taking a blood sample. The system consists of an easy-to-use saliva collection and testing cassette, used in conjunction with a small, transportable instrument. It is designed to be user friendly with minimal training required. The system is designed to quantitatively measure alcohol and test for the five National Institute on Drug Abuse (NIDA) illicit drugs (marijuana, cocaine, opiates, methamphetamine/ amphetamine and angel dust (PCP) in a single cassette from a few drops of saliva within minutes. The system is an ideal intervention tool for DUI of drugs and alcohol and provides the following advantages:

- **Delivers “under the influence” results for drugs and alcohol**
- **Provides on-the-spot results**
- **Reduces chain-of-custody issues**
- **Minimizes training requirement**
- **Eliminates transportation of suspect**

The small, transportable instrument automatically manages all functions related to running the test panel, including:

- **Specimen collection**
- **Sample adequacy and quality checks**
- **Automatic quality control and calibration**
- **Sample processing and analysis**
- **Designed to meet CLIA waivable criteria**
- **Electronic and hard copy test results**
- **Laboratory-quality accuracy and precision performance**
- **Result interpretation**
- **Legally defensible hardcopy results**



The test cassette, packaged in a foil pouch, is ready for immediate use and subsequent disposal. The saliva specimen, test reagents and waste are contained within the cassette, thereby greatly reducing the possibility of biological contamination.

The entire test procedure, including specimen collection and result printout, takes minutes. Saliva is collected via aspiration, with a device similar to those used in a dental office, and automatically transferred into the test cassette. The collection process itself takes approximately 30 – 45 seconds, which is significantly faster than absorbent pad collection (which can take five to fifteen minutes for sample collection alone). Additionally, aspiration allows for quantitative results, which cannot be provided with absorbent pad collection.

Saliva indicates blood-comparable or “under-the-influence” results, similar to a blood test. Saliva as a test specimen is therefore more relevant than urine for impairment related situations such as post-accident, for suspicion, random, and fit-for-duty tests. Urine as a test specimen indicates drug use over the last 2-5 days. LifePoint’s system is the first on-site system to test for drugs of abuse and alcohol simultaneously, and the first on-site test for blood-equivalent “under-the-influence” results. Additionally, the entire process – collection and test – is observable and significantly reduces the possibility of

adulteration.